

WELMEC 8.0

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# WELMEC

European Cooperation in Legal Metrology

## **Notified bodies Directive 2014/31/EC and Directive 2014/32/EC**

Generalities on the Assessment and Operation



# WELMEC

European Cooperation in Legal Metrology

WELMEC is a cooperation between the legal metrology authorities of the Member States of the European Union and EFTA.

This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to Notified Bodies responsible for conformity assessment of their products.

The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EU Directives.

Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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## Foreword

This document is intended to provide guidance to all those concerned with the application of the Measuring Instruments Directive (MID) and the Non-Automatic Weighing Instrument Directive (NAWID).

The guide must be considered as the general guide on the assessment and operation of notified bodies performing conformity assessment in application of MID and NAWID.

Member States are encouraged to use accreditation as a way to assess notified bodies within the meaning of and in accordance with Regulation (EC) N°765/2008 (see § 6 of Blue Guide-2014). EA has developed an advisory document (Document EA-2/17) on Accreditation for Notification Purposes. This WELMEC guide aims to provide necessary further interpretation in relation with the MID and NAWID, and is complementary to the Blue Guide.

Several other guides have been established for the detailed application of some conformity assessment modules of the two Directives. These guides should not be read without taking into consideration all relevant aspects in all the guides related to a module.

This Guide is purely advisory and does not impose any restrictions or additional technical requirements beyond those contained in the MID and the NAWID. This guide is based on the 2014 version of the Blue Guide with additions concerning possible use of EN/ISO/IEC 17065. The guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed. In principal this Guide shall be followed entirely when reference is made to it. However if some specific points of this Guide are not followed, reference to it may be made provided that these specific points are clearly identified and reasons for given.

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# 1 SCOPE

This guide is developed to assist all parties involved in the application of the MID and the NAWID:

- Notifying authorities in appointment and supervision of notified bodies (NBs),
- NBs in assessment of products and quality (management) systems, and
- Manufacturers to meet the applicable requirements.

The NBs can be assessed and operate according to this guide whether they are private bodies or part of a national or local authority.

This guide gives guidance on the use of particular quality standards within the EN ISO/IEC 17000 series for each conformity assessment module. The overall aim is that all valid combinations of the quality standards and modules featured here is giving the same confidence in the work performed by the NB.

This guide is not self-applicable. It is a top-level guide, supplemented by specific guidance. In addition to the directives themselves, operation according to this WELMEC guide may necessitate referring to several documents that are useful and recommended for the implementation of a conformity assessment module, here after called « module »:

## a) Concerning assessment of NBs:

- the most appropriate standard(s) applicable for the assessment of the competence of the Body,
- a specific WELMEC guide for the application of the relevant standard for the assessment of the competence of the Body and the relevant module (e.g. Guide 8.5 Assessment of notified bodies in charge of type examination),

## b) Concerning operation of NBs:

- a specific WELMEC guide on the global application of a module
- Where appropriate, a specific WELMEC guide on the requirements applicable to quality systems (QS) of manufacturers (e.g. Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 is applied).

This guide is mainly focusing on the modules corresponding to the procedures of conformity assessment most used in MID and NAWID (one procedure corresponds either to one single module or to a combination of two modules):

- Module B + module F,
- Module B + module D,
- Module H1,
- Module G.

## **2 Assessment and appointment of notified bodies**

### **2.1 General consideration**

Bodies are designated by the notifying authority in the Member State. The notifying authority is responsible for their assessment, designation, notification and supervision. The assessment shall be effective although all past action may be taken into account in order to facilitate the designation. The Annex 2 lists the particular requirements to be considered for renotification when the body was already notified according to the 2004/22/EC or 2009/23/EC directives.

An expert on legal metrology should always be part of the assessment team. This legal metrology expert must have competence with regard to the functioning and use of measuring instruments within the relevant field of application, the applicable assessment module(s) and the evaluation of measuring uncertainties. He must also have the knowledge of the legal requirements which are laid down for the instruments according to the directives.

### **2.2 Accreditation**

Notifying authorities are encouraged to use accreditation as a way to assess NBs within the meaning of and in accordance with Regulation (EC) No 765/2008 (see § 6 of Blue Guide-2014). It is insisted that a general accreditation cannot be regarded as sufficient: to take the accreditation into account a NB must be accredited for the specific task (for the specific measuring instrument category and the specific module of conformity assessment). However, if accreditation for the specific task is taken into account by the notifying authority and is of nature of facilitating its checking and decision, this cannot discharge the notifying authority from its responsibility regarding the evaluation of competence, decision on appointment and surveillance of the NB.

### **2.3 Relevant standards**

The recommended relevant standards for assessment of the competence of NBs are referred to in Annex 1. They can be used whether accreditation is used or not. These standards are chosen in coherence with the Blue Guide but with the addition of the reference to EN ISO/IEC 17065 for module D, D1, E, E1.

Due to the wide range of type of notified bodies (some being notified for all modules and all categories and some being only notified for module F for specific instruments) the current situation has been taken into consideration and several possible reference standards are considered appropriate by WELMEC.

### **2.4 Specific guidance**

This guide indicates (see overview in annex 1) when a specific WELMEC guide on a module exists. In that case the specific WELMEC guide shall be taken into consideration. The issue 1 of these guides are related to the previous version of MID (2004/22/EC), the issue 2 will take into consideration directives 2014/31/EU and 2014/32/EU.

Where no specific WELMEC guide exists for the application of a module, the relevant provisions in the existing specific WELMEC guides applies by analogy and shall be taken into account.

## 3 Operation of notified bodies

### 3.1 General

#### 3.1.1 Subcontracting

A NB performing product assessments may subcontract activities for which clear procedures have been established. This is in particular possible for metrological tests in order to demonstrate the performance of the instruments. Where interpretation of these procedures is necessary, the subcontractor shall contact the NB. In no case a NB may subcontract activities that necessitate:

- its expertise for which it is notified,
- Judgement on conformity of individual requirements and/or on the global acceptance of the instrument.

The MID (article 29) and the NAWID (article 25) give requirements on subcontracting by notified bodies. The “Blue Guide” provides general useful information on subcontracting and should be considered (§ 5.2.5).

#### 3.1.2 Assessment of quality management systems

A NB performing assessment and approval of quality management systems may use assessors that are not of its staff, provided the audit team fulfils the necessary requirement on the level of qualification and expertise of the assessor(s), as referred to in the MID and NAWID.

The conformity to EN ISO 9001, complemented with the appropriate specific WELMEC guide (Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 is applied), and to EN ISO/IEC 17025 for tests, gives presumption of conformity to the corresponding requirements applicable to quality systems of manufacturers.

It should be assessed that the NB has a procedure to deal with manufacturers in third countries and daughter companies in an equivalent and appropriate manner than respectively manufacturers established in the European Union and mother companies. This takes into account aspects referring to surveillance (expected and unexpected).

### 3.2 Use of standards and other WELMEC guides

WELMEC develops guides of general or specific interest other than those specific to MID/NAWID, which shall be also taken into account. The use of standards of general interest in metrology is recommended.

### 3.3 General guidance for product testing

A body fulfilling the EN ISO/IEC 17025 standard for the applicable methods will give the necessary confidence in the test results to be taken into account for the conformity assessment decision. This is applicable to tests directly performed by the NB or

subcontracted, but also to tests performed by the manufacturer in the framework of its approved quality system.

The WELMEC Guide 4.2 “Elements for deciding the appropriate level of confidence in regulated measurements” foresees that the general rule on management on uncertainties is such that the uncertainty on the test results is not greater than 1/3 of the maximum permissible error, except in the case of particular situation admitted in an international standard for example. It has to be noticed that, taking into consideration the importance of test results at the type examination or design examination stage, several OIML International Recommendations foresee that the uncertainty in the test results should not be greater than 1/5 of the maximum permissible error.

### **3.4 Type examination (module B)**

The NB operates according to EN ISO/IEC 17065, complemented by the specific WELMEC guide (Guide 8.5 Assessment of notified bodies in charge of type examination) and according to the specific general WELMEC guide on type examination (Guide 8.3 Application of Module B).

In particular, the personnel of the NB shall have adequate knowledge of the technology and applications of the instruments that are to be examined and also of the subsequent verification process.

Where appropriate the NB can take into account tests and examination performed on parts of measuring instruments performed in the framework of the WELMEC guide establishing a voluntary system of modular evaluation (WELMEC Guide 8.8).

### **3.5 Declaration of conformity to type based on product verification (module F)**

The necessary confidence will be provided by a NB operating as a type A Inspection body as defined in EN ISO/IEC 17020, complemented by the WELMEC Guide 8.7 “Assessment of Notified Bodies Designated for Module F based on EN ISO/IEC 17020”. However conformity to EN ISO/IEC 17065 is also possible, in which case the here above referred specific WELMEC Guide shall also be taken into account.

### **3.6 Declaration of conformity to type based on quality assurance of the production process (module D)**

The personnel of the NB shall have adequate knowledge of the technology and applications of the instruments that are to be examined. The competence of each person shall be documented. An expert in legal metrology having the appropriate knowledge of the category of instruments shall be part of the assessment teams.

WELMEC Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 is applied shall be considered.

### **3.7 Declaration of conformity based on full quality assurance plus design examination (module H1)**



The NB shall take into account the specific WELMEC Guide 8.2 Application of Module H1.

The implementation of module H1 necessitates 2 approvals from the same NB:

- the approval of the QS of the manufacturer,
- The issuing of a design examination certificate for each manufactured design.

The NB shall not issue a design examination certificate before having approved the quality system.

As regard to design examination, the personnel shall have adequate knowledge of the technology and applications of the instruments that are to be examined and also of the subsequent verification process. The competence of each person shall be documented.

Concerning the quality system approval, an expert in legal metrology having the appropriate knowledge of the category of instruments shall be part of the assessment teams. WELMEC Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 is applied shall be considered.

### **3.8 Declaration of conformity based on unit verification (module G)**

The personnel shall have the necessary competence in the functioning and operation of the instrument to be verified and in the legal requirements, as stated in MID and NAWID, the applicable harmonised standards or normative documents.

Where appropriate the NB can take into account tests and examination performed on parts of measuring instruments performed in the framework of the WELMEC guide establishing a voluntary system of modular evaluation (WELMEC Guide 8.8).

### **3.9 Other modules**

Where no specific guidance is provided for a module, in this guide or in another one, relevant guidance in existing guides applies by analogy.

## ANNEX 1 Overview of documents useful for the application of MID and NAWID

Module	Quality system of NB	Specific guide for assessment of bodies	Specific guide for application of the module
A	No NB	No	No
A2	EN ISO/IEC 17020 or 17065 <sup>(1)</sup> (EN ISO/IEC 17025 to be taken into account for testing)	No	No
B	EN ISO/IEC 17065 (EN ISO/IEC 17025 to be taken into account for testing)	Guide 8.5 Assessment of NBS in charge of type examination	Guide 8.3 Application of Module B
C	No NB	Not applicable	No
C2	EN ISO/IEC 17020 or EN ISO/IEC 17065 <sup>(1)</sup> (EN 17025 to be taken into account for testing) (if NB is used by the manufacturer)	No	No
D	EN ISO/IEC 17021 or EN ISO/IEC 17065	No	Guide 8.4 Application of module D
D1	(EN ISO/IEC 17025 to be taken into account for testing and EN ISO/IEC 17021 for management system auditing)	No	No
E		No	No
E1		No	No
F	EN ISO/IEC 17020 or EN ISO/IEC 17065 <sup>(1)</sup> (EN ISO/IEC 17025 to be taken into account for testing and EN ISO/IEC 17020 for inspection)	Guide 8.7 Assessment of NBs designated for Module F	Guide 8.10 Guide for generating sampling plans for statistical verification according to Annex F and F1
F1		No	
G		No	
H	EN ISO/IEC 17021	No	
H1	EN ISO/IEC 17021 + EN ISO/IEC 17065 Or EN ISO/IEC 17065 (EN ISO/IEC 17025 to be taken into account for testing and EN ISO/IEC 17021 for management system auditing)	No	Guide 8.2 Application of Module H1

<sup>(1)</sup> Concerning the alternative for A2, C2, F, F1 and G: In general the choice of one of these two standards is depending on whether the NB practices most of its activities on design certification of products (EN ISO/IEC 17065) or product verification (EN ISO/IEC 17020). But in practice a specific consideration should be paid on the complexity of the instrument's category: in the case where the study of the design is complex for application of module G, preference should be given to EN ISO/IEC 17065.

## **ANNEX 2 Specific issues to be considered for evaluation of notified bodies**

### **According to the 2014/31/EU or 2014/32/EU directives When the body was already notified according to 2004/22/EC or 2009/23/EC directives**

The requirements applicable to notified bodies are listed in particular:

- in article 27, 29 and 36 of MID
- in article 23, 25 and 31 of NAWID.

### **Notified Body for the MID**

Some requirements are wider and more detailed than in the previous version of the MID. The assessment required for re-notification shall cover in particular those requirements that are listed below:

#### ***Independence, impartiality and remuneration***

Some new activities have been added to the activities that are not compatible with the activity of conformity assessment. The activities listed in paragraph 4 of article 27 shall thus be taken into account. In particular it should be assessed that the conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the purchaser, owner or maintainer nor the representative of any of those parties.

#### ***Knowledge of the personnel responsible for carrying out conformity assessment tasks***

New requirements have been added regarding the appropriate knowledge and understanding of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, of the applicable harmonised standards and normative documents and of the relevant provisions of Union harmonisation legislation and of national legislation (see paragraph 7-c in article 27). As a consequence, the re-notification assessment should focus on these aspects and on the right understanding of the new requirements regarding:

- risk assessment
- economic operators
- The content of an EU declaration of conformity.

#### ***Policies and procedures***

Notified bodies are now required to have specific policies and procedures. It shall be checked that the policies and procedures required in paragraph 6-b and 6-c exist and are relevant.

Concerning information obtained during the conformity assessment procedures, it shall be checked that proprietary rights are protected.

#### ***Standardisation activities and activities of the notified body coordination group***

Notified bodies shall be informed of, the relevant standardisation activities and the activities of the NB coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

It should in particular be verified that the NB has a good knowledge of the WELMEC guides and of the work done at the level of NOBOMET, where applicable.

### ***Subsidiaries of and subcontracting by notified bodies***

The conformity to the requirements set out in article 29 shall be assessed, in particular the ability of the NB to keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractors or the subsidiaries and the work carried out by them under Annex II.

### ***Operational obligations of notified bodies***

Additional requirements related to proportionality and decisions following the issue of a certificate when a measuring instrument no longer complies, are set out in article 36. It should be checked that the NB procedures complies with these requirements.

## **Notified Body for the NAWID**

The provisions of Directive 2014/31/EU are much more detailed than those set out in Annex V of the previous Directive. Therefore it appears necessary for bodies that were notified only for the NAWID to conduct a comprehensive assessment of the compliance with the requirements set out in Articles 23, 25 and 31, unless they are notified also for MID and apply the same criteria for NAWID, in which case the paragraph above applies.